

REMARKS/ARGUMENTS**I. Status of the Claims**

Claims 1-5 are pending. Claims 6-17 have been withdrawn. Claims 1-5 stand rejected.

II. Statement of Substance of Interview under 37 CFR 1.133(b)

On November 7, 2008, Applicants' attorney, Shannon Powers, conducted a telephonic interview with Examiner Melanie Hand. No exhibits were utilized. Claims 1 and 2 were specifically discussed. The participants discussed amendments that had been submitted in recent responses to office actions in this file. Specifically, Examiner Hand clarified the rationale for her objections to the most recently submitted amendments, as raised in the Notice. Examiner Hand suggested restating the amendments to better indicate that the "biological fluid collection device" is a subpart of the previously examined "collection bag." Applicants' attorney accepted with appreciation these suggestions.

III. Claim Rejections – 35 U.S.C. § 102

Claims 1-3 and 5 have been rejected under 35 U.S.C. § 102(b) as being anticipated by O'Riordan *et al.* (EP 583,148 A2) ("O'Riordan"). Applicants respectfully submit that this rejection should be withdrawn.

To form a basis for a § 102(a) rejection, a prior art reference must disclose each and every element as set forth in the claim. See MANUAL OF PATENT EXAMINING PROCEDURE ("MPEP") § 2131 (Rev. 6, 2007). "The identical invention must be shown in as complete detail as it is contained in the claim." *Id.* "The elements must be arranged as required by the claim." *Id.* With regard to independent claim 1, O'Riordan fails to disclose every element of the claims.

O'Riordan fails to disclose, at least, *allowing a biological fluid to flow through a biological fluid collection device of a collection bag to the collection bag without the use of a pump*, as required by amended independent claim 1. In fact, O'Riordan explicitly limits the disclosure to embodiments that include a pump means for conveying fluid from the blood

receiving means to the blood reservoir. O'Riordan at 3, lines 25-27. In order to anticipate, O'Riordan would have to disclose an embodiment that does not include a pump. O'Riordan, however, fails to disclose any embodiments that do not include a pump.

Accordingly, Applicants submit that O'Riordan cannot anticipate Applicants' claims as set forth in independent claim 1. The remaining claims rejected as anticipated by O'Riordan under 35 U.S.C. § 102(a) depend either directly or indirectly from independent claim 1. All these dependent claims include all the limitations of their corresponding independent claim 1. Accordingly, Applicants respectfully request withdrawal of this rejection with respect to claims 1-3 and 5.

IV. Claim Rejections – 35 U.S.C. § 103

Claim 4 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over O'Riordan et al (EP 583,148 A2). Applicants respectfully submit that this rejection should be withdrawn.

The examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. MPEP § 2142. The examiner must show that the claimed invention “as a whole” would have been obvious to a person of ordinary skill in the art when the invention was unknown and just before it was made. *Id.* The showing must be made on the basis of the facts gleaned from the prior art without resorting to hindsight based upon applicant’s disclosure. *Id.* All of the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). ““[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.”” *KSR International Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1741, 82 USPQ2d 1385, 1396 (2007) quoting *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006).” MPEP § 2143.01.IV.

The Office Action fails to state a *prima facie* case of obviousness. As previously discussed, O'Riordan fails to disclose, at least, *allowing a biological fluid to flow through a biological fluid collection device of a collection bag to the collection bag without the use of a pump*. Additionally, O'Riordan does not teach or disclose the limitation of *calculating the variation in weight of the fluid collected*, as required by claim 4. The Office Action

acknowledges that O'Riordan does not teach "that measuring a fluid flow rate of the biological fluid comprises calculating the variation in weight of the fluid collected". Office Action, p. 7. The Office Action makes the unsupported statement that,

[I]t would be obvious to one of ordinary skill in the art to modify the method taught by O'Riordan such that the step of measuring fluid flow rate Q_b further comprises the step of calculating the variation in weight of fluid collected with a reasonable expectation of success to monitor the amount of fluid collected to determine when a sufficient amount of blood has been collected and the process can be stopped.

Id. Rather than showing how O'Riordan could be modified to use a variation in weight of the fluid to measure the fluid flow rate (as required by claim 4), this statement shows how O'Riordan could be modified to perform a superfluous calculation, that being converting fluid volume to fluid weight. The method disclosed in O'Riordan does not require conversion of fluid volume to weight to monitor the amount of fluid collected. The addition of this superfluous step only increases the likelihood of unintentional errors, and thus cannot provide a reasonable expectation of success. The suggested modification of O'Riordan, therefore, does not make obvious the limitation of claim 4. Since O'Riordan fails to teach or disclose either *allowing a biological fluid to flow through a biological fluid collection device of a collection bag to the collection bag without the use of a pump* or *calculating the variation in weight of the fluid collected*, the Office Action fails to state a *prima facie* case of obviousness. For at least these reasons, Applicants respectfully request the withdrawal of the rejection of claim 4.

V. Provisional Rejections – Double Patenting

Claims 1-5 have been provisionally rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 15-21 of copending application No. 11/196,706 ("Copending Application"). Applicants respectfully submit that this rejection should be withdrawn.

The Copending Application was filed August 3, 2005, subsequent to filing of the instant Application. Therefore, the instant Application is the earlier-filed of the two. As Applicants believe the amendments and remarks herein have otherwise put this application in a condition for allowance, MPEP § I.B.1 instructs that "the examiner should withdraw [the

nonstatutory obviousness-type double patenting] rejection and permit the earlier-filed application to issue as a patent without a terminal disclaimer."

For at least these reasons, Applicants respectfully request the withdrawal of the provisional rejection of claims 1-5.

VI. Conclusion

In light of the above amendments and remarks, which are supported by the specification, Applicants respectfully request reconsideration and withdrawal of the outstanding rejections. Applicants further submit that the application is now in condition for allowance, and solicit timely notice of the same. Should the Examiner have any questions, comments, or suggestions in furtherance of the prosecution of this application, the Examiner is invited to contact the attorney of record.

Applicants believe that no additional fees are due. However, should the Commissioner deem that any fees are due, the Commissioner is authorized to debit Baker Botts L.L.P. Deposit Account No. 02-0383, Order Number 062908.0115, for any payment of associated fees, underpayment of fees, or to credit same with any overpayment of fees that may occur in association with this filing.

Respectfully submitted,



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